

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re application of: | Shinya Nakajima | Docket: | 102501-200 |
| Serial No.: | Not yet received | Art Unit: | Not yet received |
| Filed: | Herewith | Examiner: | Not yet received |
| Assignee: | Shinya Nakajima | | |
| Title: | MEDICINES INCLUDING INTERFERON AND ADMINISTERING SYSTEM THEREOF | | |

Certificate of Mailing

Date of Deposit: October 15, 2003

I hereby certify under 37 CFR 1.8(a) that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signed: _____

Name: Elizabeth A. Geschke

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, please find enclosed an Information Disclosure Statement, Form PTO-1449 and one copy of each cited reference. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required.

- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- ☐ a. Each item of information contained on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(1); and no fee is required under 37 C.F.R. §1.17(p).
- ☐ b. No item of information cited on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2); and no fee is required under 37 C.F.R. §1.17(p).
- ☐ Please charge Deposit Account No. 23-1665 in the amount of \$180.00 in payment of the fee under 37 C.F.R. §1.17(p). Two additional copies of this Information Disclosure Statement are enclosed.
- ☐ A check in the amount of \$180.00 is attached hereto in payment of the fee under 37 C.F.R. §1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered.
- ☐ a. Each item of information contained on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application

not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(1).

☐ b. No item of information cited on Form PTO-1449 filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2).

☐ Please charge Deposit Account No. 23-1665 in the amount of \$130.00 in payment of the fee under 37 C.F.R. §1.17(i)(1). Two additional copies of this Information Disclosure Statement are enclosed.

☐ A check in the amount of \$130.00 is attached hereto in payment of the fee under 37 C.F.R. §1.17(i)(1).

The undersigned represents that the closest art of which he is presently aware has been cited herein and understands that this statement shall not be construed as a representation that no better art exists or that a thorough patentability search has been made.

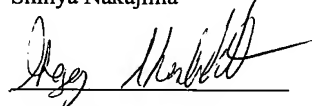
The undersigned further represents that the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

Date: October 15, 2003

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One Century Tower
New Haven, CT 06508-1832
Telephone: (203) 498-4566
Facsimile: (203) 782-2889

Respectfully submitted,

Shinya Nakajima



Gregory S. Rosenblatt
Reg. No. 32,489

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Serial No.: | Not yet received | Art Unit: | Not yet received |
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Signed: _____

Name: Elizabeth A. Geschke

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

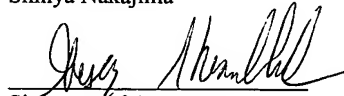
In keeping with the duty of candor and good faith owed to the Patent and Trademark Office, Applicant wishes to make of record the items on attached PTO Form 1449 which were considered in the preparation of the subject application. Copies of the items are provided in accordance with 37 CFR §1.98.

1. Kawamura, Chika et al., "Two-dimensional Analysis of Production of IL-6 and TNF- α can Predict the Efficacy of IFN- α Therapy," *Hepato-Gastroenterology*, vol.46, pp.2941-2945, 1999 .

The undersigned represents that the closest art of which he is presently aware has been cited herein and understands that this statement shall not be construed as representation that no better art exists or that a thorough patentability search has been made.

Date: October 15, 2003

Respectfully submitted,
Shinya Nakajima

A handwritten signature in black ink, appearing to read 'Gregory S. Rosenblatt', is written over a horizontal line.

Signature of Attorney
Gregory S. Rosenblatt
Reg. No. 32,489

WIGGIN & DANA LLP
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New Haven, CT 06508-1832
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FORM PTO-1449

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|---|-----------------|------|--------------------------------|------------------|--------------------------------|----------------------------|
| INFORMATION DISCLOSURE | | | ATTY. DOCKET NO. 102501-200 | | SERIAL NO. NOT YET RECEIVED | |
| | | | APPLICANT: SHINYA NAKAJIMA | | | |
| | | | FILING DATE: HEREWITH | | GROUP: | |
| U.S. PATENT DOCUMENTS | | | | | | |
| EXAMINER INITIALS | DOCUMENT NO. | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPR. |
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| FOREIGN PATENT DOCUMENTS | | | | | | |
| EXAMINER INITIALS | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO |
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| OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) | | | | | | |
| Kawamura, Chika, "Two-dimensional Analysis of Production of IL-6 and TNF- α can Predict the Efficacy of IFN- α Therapy," <i>Hepato-Gastroenterology</i> , vol. 46, pp. 2941-2945, 1999. | | | | | | |
| EXAMINER: | | | | DATE CONSIDERED: | | |
| <small>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small> | | | | | | |